



RESEARCH PROTECTIONS UPDATE



News and Comments on the Protection of Human Subjects in Navy and Marine Corps Research

Volume 10, Number 4

December 2020

Special Feature

Applying the 4'Ps to Human Research Protection

By Rear Adm. Bruce L. Gillingham



Last year I was honored and privileged to take the helm and represent you as the 39th Surgeon General of the Navy, as well as the single point of accountability for the Department of the Navy Human Research Protections Program (DON HRPP). At that

time, I outlined Navy Medicine's strategic priorities: People, Platform, Performance, and Power. The "4P's" is our roadmap to meet both the challenges of today and those that we will face in the future. It is through the 4P's that we will achieve maximum contribution to Naval superiority and achieve Navy Medicine's primary objective: medical readiness. One of the ways that we continue to directly improve not only our own readiness, but also the readiness of those that we support in the Navy and the Marine Corps is through human subjects research. Research aids Navy Medicine in staying agile, it enables us to adapt, and it ensures that we thrive now, and in the future. I would like to take this opportunity to apply the 4P's that guide my priorities to the concept of human subjects research.

Research People: Our military and civilian workforce is our greatest strength. People remain the first "P" for a reason, and that is because all the people in Navy Medicine are the foundation upon which all of our success is built. Our military and

civilian personnel participating in research and those involved in protecting the rights and welfare of human research participants contribute to the strength of our Navy. Our research volunteers, institutional officials, ethical review board members, researchers, research administrators and research support staff are all vital in contributing to our core mission of producing force medical readiness. It is the lessons learned from past examples of unethical human research that our current ethical principles and regulations governing human research is built upon. It remains of utmost importance to protect the rights and safety of all participants in DON conducted or supported research. Although the history of human research provides numerous examples of immoral practices in research, it is important to note that the lack of contemporary incidences prove that continued efforts in human research protection programs and policies are effective safeguards. With additional considerations for special populations, for example, children, women,

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disadvantaged persons and military personnel, our researchers continually strive to contribute to excellence through Navy research.

Research Platforms: Our equipment and capability sets required by our warfighters drive research platform development. Almost without exception, no organization, no matter the industry, can afford to look away from technology and the need for greater digitization. In no sector is this more applicable than healthcare where artificial intelligence (AI) and machine learning, precision robotics, telemedicine, wearables, Electronic Medical Records (EMRs) and data science techniques are augmenting an already extensive array of scanners, surgical equipment, monitors and other advanced technologies. This wave of automation is changing the landscape and shaping the future of medicine; a future in which collaboration between human and machine will rapidly accelerate. Human machine teaming has reached its prolific level of presence today through decades of human subjects research. Whether developing echo-free chambers or soundproof booths essential to work in hearing conservation, or pioneering audio signal enhancement for diver hearing at NSMRL or aiding our warfighters through the Computer Assisted Rehabilitation Environment (CAREN) of NHRC, protecting human subjects as they use our research platforms remains vital.

Research Performance: Our performance is measured by our support to our warfighters. We use data driven decisions to optimize medically ready forces. DON research enhances warfighter performance in a myriad of areas, such as operator and weapon system integration, human factors engineering, protective clothing and devices development, shipboard and submarine training, viral and parasitic disease prevention and treatment, aerospace and aeronautical medicine, diving and submarine medicine and research, combat casualty care and management, diversity, inclusion and organizational behavior. Optimum research performance is not possible without optimum human research protection, ensuring that participants are fully aware of the risks and benefits that come hand in hand with the cutting edge of innovation. Researchers are the core of our culture of never being content, always pushing forward and advancing as an organization. With high reliability research, we provide the best possible environment for our warfighters to fight and win.

Research Power: Medical power projection will increase survivability. Every action and investment we make will contribute to our core mission of producing force medical readiness. We leverage our world-class research enterprise on cutting edge medical knowledge, and developing solutions for the warfighter. This research provides the power to increase force medical readiness. Research power is also a form of diplomacy, as DON research on infectious diseases benefits people living in the countries where the diseases are endemic. As the COVID-19 pandemic continues to challenge the Navy and the world, I am particularly proud of our Navy Marine Corps Public Health Center and Naval Medical Research Center in that we were able to have two articles published on Veteran's Day in the New England Journal of Medicine. The first was a comprehensive study of the COVID-19 outbreak that occurred aboard the Theodore Roosevelt—an excellent epidemiologic report of that outbreak. The second was a prospective study looking at COVID-19 impact and COVIN immunology on recruits at Paris Island. This study has significant implications beyond military lifelines for young adults who are in congregate settings, and will benefit the security of our Civilian friends. These articles demonstrate the power of our research and public health enterprise, serving as a great dividend to the United States taxpayer for the money that they have invested in us to do this important work, ensuring the maximum safety of our study participants. As is said, knowledge is power; research facilitates this knowledge, and results in the production of medical power.

In conclusion, the “4P’s” of research will contribute to our roadmap to meet both the challenges of today and those that we will face in the future. Whether ensuring research subjects retain their dignity and respect (**People**), using research to maximize human machine interaction (**Platforms**), ensuring that research serves its intended warfighter population (**Performance**), or leveraging the findings that arise from research (**Power**), human subject’s research, to include the safety of human subjects, is a critical component of the Navy’s future. Thank you for all that YOU do every day to project medical power in support of naval superiority.

With my respect and admiration, SG



DIRECTOR'S CORNER

This year has been one to remember. A year full of challenges which include a global pandemic, civil unrest, wildfires, deep political differences, and an economic recession. However, despite these challenges, the Department of the Navy human research protection program enterprise has remained steadfast in its mission to protect and maintain the wellbeing of human subjects in research while also maintaining the wellbeing of ourselves. The COVID-19 pandemic has had, and continues to have, a great impact on the way we do business as social distancing has affected our interactions with each other and our interactions with human subjects. Commands engaged in human subject research have had to reevaluate their processes and implement safety plans to ensure the welfare of their subjects and their staff. I have seen great innovation in the various ways this is being accomplished and I am ever grateful for your dedication. Your commitment and resiliency is an example of Navy excellence!

For our final newsletter this year, we have the great honor of the SG's contribution. I am privileged to facilitate the SG's strategic priorities, the "4Ps"; People, Platforms, Performance and Power, as it relates to human research protections. These priorities are a guide to how we operate and contribute to medical readiness and maritime superiority.

Also, in this issue of the newsletter, we take the opportunity to acknowledge and celebrate the following individuals for their very many years of service to Navy human research protections; Ms. Debra "Debbie" Bachman and Dr. William "Bill" Becker. Both Ms. Bachman's and Dr. Becker's service in Navy HRPPs have been exceptional and commendable. We appreciate the opportunity to highlight their work in human research protections and we find value in the thoughts they have both shared through DON HRPP interviews. Congratulations on your retirement and our sincerest well wishes on this next chapter of your lives!

Finally, we celebrate the following past observances, National Disability Employment Awareness Month (1st - 31st October) and American Indian Heritage month (1st – 30th November). Through these observances, we acknowledge the many contributions of American Indians and persons with disabilities; serving with bravery in our nation's struggles, aiding in our nation's success. By recognizing these observances, we reaffirm our commitment in supporting equal opportunity for all citizens. I welcome feedback, suggestions and comments on how DON HRPP can be of better service to the HRPP community in the New Year and beyond.

-CDR Leedja Svec



For more ways to celebrate diversity, please see observance materials provided by the Defense Equal Opportunity Management Institute at <https://www.defenseculture.mil/>

Fair Winds & Following Seas

DON HRPP Interviews Debbie Bachman of Naval Research Medical Unit- Dayton (NAMRU- Dayton)



DON HRPP: Can you provide us a brief history of your professional experience in human research protections? How long have you been involved and what roles have you held?

Bachman: I started my professional career in human subject protection working for the Air Force at the Wright-Patterson Medical Center as a Clinical Investigations Coordinator in October 1992. I was detailed to the position for one year then offered the position as permanent. I also served as the non-scientific IRB member for the medical center. I held this position until February 2011 when I started my position as Research Program Specialist at the Naval Medical Research Unit Dayton. In this role I serve as the IRB Administrator and as the non-scientific IRB member on the NAMRU-D IRB. I'm also the Human Research Protection Official (HRPO) for NAMRU-D and the HIPAA Compliance Officer.

DON HRPP: What has been the most challenging part of your role in human research protections?

Bachman: One of the biggest challenges I've had to overcome is limited staffing with a growing research program. My position was the only full-time position with all board members and IRB Chairs serving as an additional duty. Our command has grown significantly over the last 5 years along with the amount of research. Luckily my command saw the need for additional support and was able to provide relief. A few years ago we also implemented eIRB which also helped to streamline our processes. The rewards have far exceeded the challenges faced in this position.

DON HRPP: What has been the most rewarding part of your role in human research protections?

Bachman: I have always known how much medical research has helped to improve people's lives. I know how important the job of protecting those who

DON HRPP Interviews Dr. Bill Becker of Naval Health Research Center (NHRC)



DON HRPP: Can you provide us a brief history of your professional experience in human research protections? How long have you been involved and what roles have you held?

Becker: As a young and new scientist working for the Navy much of my research was under HRPP review and at the time I felt that they made research harder than it had to be. So after a couple years, I volunteered to be an IRB member and my view quickly began to change. Since then I moved from board member to Vice Chair then to Chair. I also serve as an outside board member for other commands. I have been involved in human subject protections for roughly 20 years at 5 different commands with differing kinds of research needs.

DON HRPP: What has been the most challenging part of your role in human research protections?

Becker: The first most challenging part was the transition from just a researcher to a researcher/IRB member. You tend to start the role with your preconceived ideas of how they do it and how you want to change it. If like me when you start you want to know all of the laws, instructions, and guidance so that you can put together a plan backed up by knowledge to change "them", you learn that the regular training you are required to take as a researcher only just dusts the top of what is the human research protections program. This is especially true working inside of the DoD research community which has their own slight twist.

DON HRPP: What has been the most rewarding part of your role as IRB Chair?

Becker: As the Chair, the most rewarding part has been getting the research teams to understand why I make them change, adjust or adapt their research proposals. That it is not "do as I say if you want your research approved" (though that is how it usually starts

DON HRPP Interviews Debbie Bachman (Continued from page 4)

volunteer to participate in research is, and I feel privileged to do it. I also know from the participant prospective how important research is in today's society. I have participated in several research studies during my life.

DON HRPP: Human subject research (among so many other things), has been impacted by the COVID-19 pandemic. Where do you see the future of HSR?

Bachman: I believe we've all done a wonderful job when it comes to protecting human subjects in the research arena. However, after COVID struck, it forced us to take a closer look at how we accomplish this and how to protect the research staff as well as the research subjects. In some cases research that involved subject interaction was put on hold until processes could be changed to further protect all those involved in the research. I think flexibility is important to the future of HSR.

DON HRPP: There has been several regulatory changes in human research protections in the last few years to include changes to the Common Rule, DoDI 3216.02 and SECNAV instruction. Do you have any advice on navigating these changes?

Bachman: With the many regulatory changes that have occurred within the past few years come many questions. Having our oversight there to answer these questions has been extremely helpful in navigating the many changes. Keeping everyone involved in the research informed of all upcoming changes has been important. As well as making changes to policies and procedures where necessary. Keeping your compliance program up-to-date to ensure continuing compliance with regulatory changes is paramount.

DON HRPP: Finally, with your many years of experience, do you have any words of wisdom to impart upon us before your retirement?

Bachman: After 35 years and working for three services I am looking very forward to the next chapter in my life. Always look forward to what's coming next, things will never stay the same.

DON HRPP Interviews Dr. Bill Becker (Continued from page 4)

out) but they begin to understand why you ask for the changes. They understand that the changes not only protect the subject from harm but will protect the research team from possible lawsuits. The best is when they call you as they put a plan together and ask for guidance on "If we do X, how does that affect Y?" In my current role, I've reduced the review cycle from 2-3 weeks of back and forth with the research team to 3-5 days.

DON HRPP: Human subject research (among so many other things), has been impacted by the COVID-19 pandemic. Where do you see the future of HSR?

Becker: All of our person-to-person contact has been halted in favor of more virtual interactions. This in its self poses new challenges because now a days we not only have to protect the health of the individual but protect all of the information and biospecimens that relate to an individual. DoD medical research is transitioning from individual medical research sites to being housed under a central authority which will bring even more changes to how we perform oversight of HSR. The future continues to hold many changes.

DON HRPP: There has been several regulatory changes in human research protections in the last few years to include changes to the Common Rule, DoDI 3216.02 and SECNAV instruction. Do you have any advice on navigating these changes?

Becker: The hardest part of some of these changes is that they are made without letting the research community know. I suggest annually at least (I do it every 6 months) do a general search for the most important documents. Reach out to HSR folks at other commands even other services and talk to them about the whole process. This way if there are any changes you can catch them. A good example is if you are in the medical research side of DoD HSR there is the possibility of transitioning to oversight by DHA. They use a different model for oversight than DON HRPP, they abided by the same rules they just execute in a different manner. If you haven't begun the process to understand their model I suggest you contact an MTF to get some insight.



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DON HRPP Interviews Dr. Bill Becker

(Continued from page 5)

DON HRPP: Finally, with your many years of experience, do you have any words of wisdom to impart upon us before your retirement?

Becker: I've enjoyed being part of the ever-changing scenery of research in DoD throughout my career and seeing changes as they happen. I miss being a researcher but being on the administrative end I got to see the broader view of changes and why they were being made.

I was involved in research before the first Gulf War and it was an exciting time in human subjects' research in terms of developing ways to protect our military personnel. I was on the IRB at Navy Research Lab (NRL) and able to see different projects outside of human subjects research which gave me a good perspective later. My big take away is communicate, reach out to other HSR folks and talk about everything. It might prepare you for that next situation.

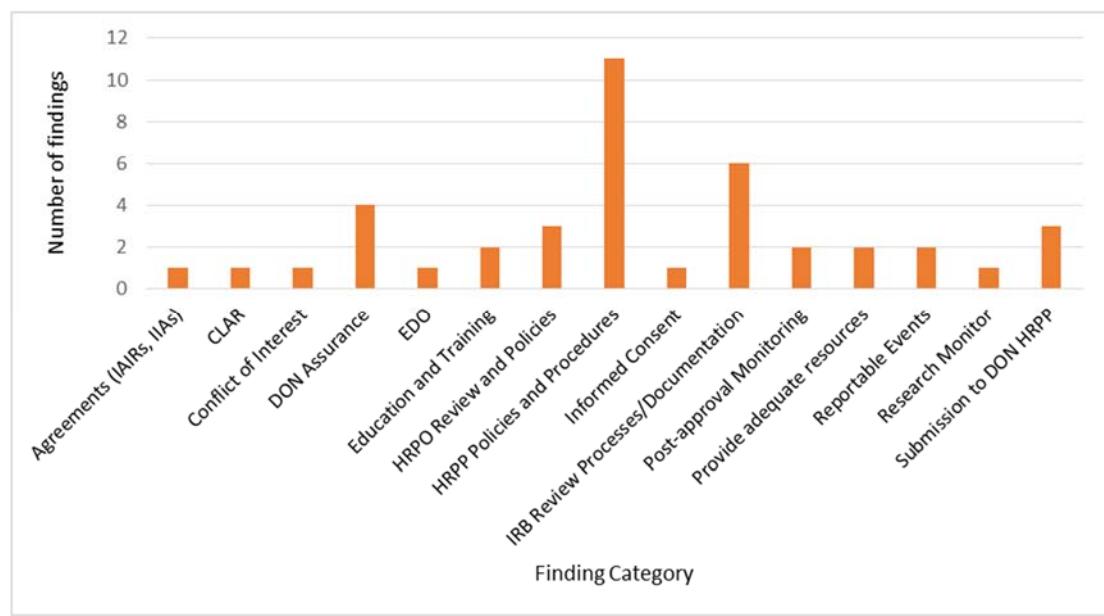


DON HRPP Quality Assurance Activities

To quote the American mathematician John Tukey "the greatest value of a picture is when it forces us to notice what we never expected to see". This statement reflects the value of data and the information that it provides. With an eye towards improving processes and increasing the ability to make data driven decisions, DON HRPP added a position dedicated to Quality Assurance (QA) and increased its QA related activities during 2020. The QA specialist spends time and effort to review annual analysis of site visit findings, a quarterly analysis of internal data (such as timeline adherence and reviews completed), and an annual review of DON HRPP's internal standard operating procedures (SOPs). DON HRPP is working to further develop and expand QA activities in an effort to look at DON compliance trends, measure DON HRPP performance, and improve DON HRPP processes. As Carly Fiorina former CEO of HP notes, "The goal is to turn data into information, and information into insight". In this spirit of facilitating insight, DON HRPP presents in the graph below a summary of findings in 2019 by category across the DON, where it is evident that the top three categories are DON HRPP Policies and Procedures, HRPP Review Processes/Documentation, and DON Assurance. It will be interesting to see what 2020 illustrates; as further analysis will support efforts to target the needs and realities of Commands in support of DON HRPP's vision to preserve the rights and welfare of human subjects in the Navy and Marine Corps.

As DON HRPP works to measure what matters, examining 2020 in sum shows in Table 1 (next page) the number of Headquarters level submissions received, command visits conducted, administrative oversight engaged, amount of training offered and number and type of communications sent, as well as other measures. As DON HRPP looks to continue serving the Navy and Marine Corps in 2021, DON HRPP will use objective data to guide the way.

Figure 1. Total Visit Findings with Required Actions by Category FY2019



DON HRPP Quality Assurance Activities (*continued from page 6*)**Table 1. Summary of DON HRPP Operations 2020**

Function	Outcome
Headquarter Level Submissions (Estimated)	1,394 protocol actions reviewed 96 IRB meeting minutes reviewed
Command Visits	2 Site Inspections, 1 Courtesy Visit, 7 Offsite Reviews/ Virtual Visits conducted
Human Research Protocols (Estimated)	660
Administrative Oversight	25 Assurance Packages 13 Component-level admin review packages
Communications	15 E-Grams sent 3 DON HRPP Newsletters sent (Mar, Jun, Sep 2020) 1 DON HRPP milSuite site launched
Education Training Offered	9.5 hours
Internal SOPs Updated/Created	17

WELCOME!!**New Members In The Office of Naval Research's (ONR) DON HRPP Team**

DON HRPP welcomes new Human Research Compliance Specialists, Ms. Heather Hermann and Ms. Ashleigh Gill to ONR's Research Protection Division.

Ms. Hermann joined ONR in September 2020. Prior to joining ONR, Ms. Hermann spent six years as the Corporate Research Compliance Officer for the Order of Saint Francis (OSF) Healthcare System in Peoria, Illinois. She holds a Master of Jurisprudence Degree in Compliance and Risk Management, is a Certified Institutional Review Board (IRB) Professional (CIP®), and actively holds the Certified in Healthcare Research Compliance (CHRC®) credential. Ms. Hermann has over 10 years of experience with human research protections in biomedical, social, and behavioral research. In addition to her years at OSF Healthcare System, she also held IRB education, accreditation, and compliance specialist positions at the University of Iowa Human Subjects Office and the University of Illinois College of Medicine Office of Human Research Oversight. Ms. Hermann comes to DON HRPP with significant experience in auditing, research misconduct, grants, research billing & contracts, and HIPAA compliance. Prior to her work in human research protections, Ms. Hermann spent 10 years in the biotech field as a production scientist and technical support manager at Integrated DNA Technologies where she provided client support in the design and manufacture of custom modifications for synthetic DNA and RNA, troubleshooting for molecular biology applications, gene opti-

mization services, and managed a staff of 30 technical support specialists based on the United States and Belgium. Ms. Hermann also provided quality assurance services to Biotech Pharmaceuticals with a regulatory focus on the manufacture of biologics for use in humans.

Ms. Gill joined ONR in September 2020. Prior to joining ONR, Ms. Gill worked at The National Human Genome Research Institute (NHGRI) in Bethesda, Maryland. She holds a Bachelor's of Science Degree in Biology and a Master's of Science Degree in Biohazardous Threat Agents and Emerging Infectious Diseases. While at NHGRI, she performed full-time biomedical research on genetic syndromes, specifically Noonan, Williams-Beuren, and Turner syndromes. In addition to biomedical research, she studied health disparity issues among persons with different origins and backgrounds in order to identify and understand genetic disorders that are unique to subpopulations and socioeconomically disadvantaged communities.

Farewell

Ms. Amber Gunn-Westland departs from DON HRPP. Ms. Gunn-Westland came on board with DON HRPP in September 2017 as a Human Research Compliance Analyst. DON HRPP is very appreciative for all the hard work Ms. Gunn Westland provided to the Naval Medical Research Center Asia (NMRC-A)/Naval Medical Research Unit Two (NAMRU-2) HRPP, as well as numerous other Commands during her years at DON HRPP. DON HRPP wishes Ms. Gunn-Westland the best in her future endeavors



DON HRPP News!!

- The Department of the Navy Human Research Protection Program (DON HRPP) developed a spreadsheet that highlights some of the requirements that changed due to the revised DoDI 3216.02. This spreadsheet, titled *DON HRPP List of Revised DoDI Sections Oct 30_2020*, is available at the DON HRPP milSuite site and will be updated as new insights are gained. For direct access to the spreadsheet, please click here: <https://www.milsuite.mil/book/docs/DOC-895893>. If access to milSuite is not available, please contact DON HRPP for assistance.
- DON HRPP participated in the DoD Office for Human Research Protections (DOHRP) Forum of discussions on DoD human research protection programs, the revised Common Rule, and the revised DoDI 3216.02 held via teleconference on 18 November 2020. On 1 December 2020, a DON HRPP E-gram provided an overview of the information presented by the DOHRP during the forum. For direct access to the document please click here: <https://www.milsuite.mil/book/docs/DOC-906847>

We Need Your Help!**Get a BZ from RPU**

Have a "Good News" story or picture from your Research Protection Program? Don't keep it to yourself! Why not share it with the DON Research Protection community? We're looking for material to publish in the *Research Protections Update* newsletter. Send your research news, success stories, tips, pictures, lessons learned, or other material related to the ethical conduct of human research to usn.ncr.bumedfchva.mbx.don-hrpp@mail.mil.

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**DON HRPP Wishes
You a Safe and
Happy New Year!!**